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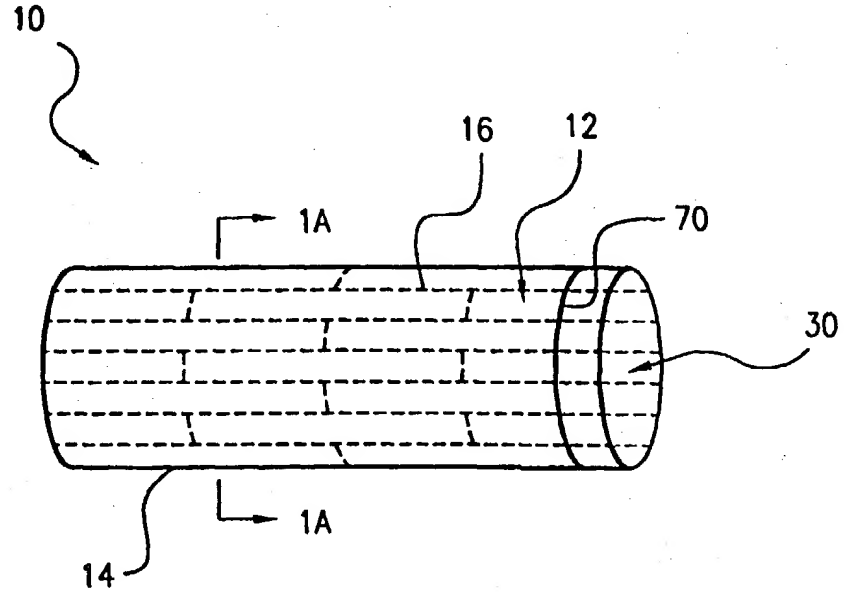

(57) Abstract

An expandable prosthesis includes a self-expanding stent deployable between a substantially radially compressed configuration and a substantially radially expanded configuration. A biocompatible coating is attached to at least a portion of the outer surface of the self-expanding stent in the radially compressed configuration to inhibit radially expansion of the self-expanding stent to the radially expanded configuration. The biocompatible material is preferably integrally mounted to the self-expanding stent thus eliminating the need for a separate, independent delivery tube or sheath for maintaining the self-expanding stent in the radially compressed configuration during delivery of the self-expanding stent into a body vessel.

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SELF-EXPANDING PROSTHESIS WITH BIOCOMPATIBLE COATING

Background of the Invention

The present invention relates to expandable intraluminal prostheses for use in body passages, and more particularly, to self-expanding intraluminal prostheses useful for the treatment of body passages, such as blood vessels, occluded by disease.

Self-expanding prostheses are commonly used to restore and maintain the patency of body passages, particularly blood vessels. Self-expanding prostheses include stents constructed from shape memory materials, such as Nitinol, stents constructed of conventional materials, such as stainless steel, in a configuration that exhibits self expansion characteristics, and other varieties of prostheses. Such self-expanding stents can be compressed into a reduced diameter state suitable for percutaneous insertion into the body passage through a catheter. The self-expanding stent is typically held in the reduced diameter state until delivery into the body passage, whereupon the self-expanding stent is released to an increased diameter state within the body passage to hold open the body passage.

Problems associated with such conventional self-expanding stents include the need for pre-dilation of the body vessel, typically with a catheter-deployed balloon, prior to deployment of the self-expanding stent. Pre-dilation of the body vessel is necessary because the self-expanding stent alone frequently lacks sufficient radial expansion strength to completely open the diseased body vessel. Additionally, post-dilation of the self-expanding stent can be necessary to ensure the self-expanding stent has deployed to a sufficient diameter to engage the walls of the blood vessel. The need for pre- and post-dilation increases the duration of the medical procedure and the risk to the patient.

Additionally, conventional self-expanding stents generally require a separate containment system, for example a delivery tube or sheath, that radially constrains the stent in the reduced diameter state during catheter delivery and until the stent is deployed within the body vessel. Frequently, the self-expanding stent moves within the

body vessel as the containment system is removed, adversely effecting the accuracy of the deployment of the stent within the body vessel. Moreover, the removal of the delivery sheath once the stent is in place requires an additional step, prolonging the medical procedure and, thus, the risk to the patient.

Summary of the Invention

The present invention provides an expandable prosthesis that includes a self-expanding stent deployable between a substantially radially compressed configuration and a substantially radially expanded configuration. A biocompatible coating is attached to at least a portion of the outer surface of the self-expanding stent in the radially compressed configuration to inhibit radial expansion of the self-expanding stent to the radially expanded configuration. The biocompatible material is preferably integrally mounted to the self-expanding stent thus eliminating the need for a separate, independent containment system, such as a delivery tube or sheath, for maintaining the self-expanding stent in the radially compressed configuration during delivery of the self-expanding stent into a body vessel.

The self-expanding stent is preferably constructed from a material having shape-memory properties such as an alloy of nickel and titanium, (e.g. Nitinol). The biocompatible coating is preferably expanded polytetrafluoroethylene (ePTFE) and can extend between the first and second ends of the self-expanding stent. In addition, the biocompatible coating can be folded-over the first end and/or the second end of the self-expanding stent and can be attached to at least a portion of the inner surface of the self-expanding stent. In a preferred embodiment, the biocompatible coating is attached to the inner and outer surfaces and extends between the first and second ends of the stent to encapsulate the self-expanding stent.

In accordance with an alternative embodiment of the present invention, the expandable prosthesis includes a self-expanding stent deployable between a substantially radially compressed configuration and a substantially radially expanded configuration

and a plastically deformed, expanded biocompatible coating attached to the outer surface of the self-expanding stent.

In accordance with another embodiment of the present invention, the expandable prosthesis includes a self-expanding stent having a first diameter which permits delivery of the self-expanding stent into a body passage and a second, expanded diameter suitable for treatment of the body passage. A layer of biocompatible material is attached to at least a portion of the outer surface of the self-expanding stent that is deformable between a first state sized to restrain the self-expanding stent to the first diameter, and a second, expanded state. the layer deforming to the second, expanded state upon expansion of the self-expanding stent to the second diameter by a radially, outward extending force.

A method of forming the expandable prosthesis of the present invention includes the steps of providing a self-expanding stent that is deployable between a substantially radially compressed configuration and a substantially radially expanded configuration and coating the self-expanding stent in the radially compressed configuration with a biocompatible material to retain the stent in the radially compressed configuration. Preferably, at least a portion of the outer surface of self-expanding stent is coated with the biocompatible material. Additionally, at least a portion of the inner surface of the self-expanding stent can be coated with the biocompatible material.

A method of deploying an expandable prosthesis in a body passage in accordance with the teachings of the present invention includes the steps of providing an expandable prosthesis that includes a self-expanding stent that is deployable between a substantially radially compressed configuration and a substantially radially expanded configuration. A biocompatible coating is attached to at least a portion of the outer surface of the self-expanding stent. The prosthesis is disposed on a catheter and the prosthesis and the catheter are inserted within the body passageway. The biocompatible coating retains the self-expanding stent in the radially compressed configuration in the absence of an external, radially outward force on the self-expanding stent.

In accordance with one aspect of the present invention, the prosthesis is expanded at a desired location in the body passage by applying a radially outward force on the prosthesis to place the biocompatible material into contact with the body passage. The step of expanding the prosthesis radially deforms the biocompatible coating beyond its elastic limit. The radially outward force on the prosthesis can be provided by inflating a catheter-deployed balloon within the self-expanding stent.

Brief Description of the Drawings

These and other features and advantages of the present invention will be more fully understood by reference to the following detailed description in conjunction with the attached drawings in which like reference numerals refer to like elements through the different views. The drawings illustrate principles of the invention and, although not to scale, show relative dimensions.

FIGURE 1 is a perspective view of the expandable prosthesis of the present invention;

FIGURE 1A is a side elevational view in cross section of the expandable prosthesis of FIGURE 1, taken along the line 1A-1A of FIGURE 1;

FIGURE 2A is a perspective view of the self-expanding stent of the expandable prosthesis of FIGURE 1; illustrating the self-expanding stent in the radially compressed configuration;

FIGURE 2B is a perspective view of the self-expanding stent of the expandable prosthesis of FIGURE 1, illustrating the self-expanding stent in the radially expanded configuration;

FIGURES 3A-C are perspective views of the self-expanding stent of the expandable prosthesis of FIGURE 1, illustrating a method of manufacturing the self-expanding stent;

FIGURE 4 is a flow chart illustrating the process of manufacturing the self-expanding stent of the expandable prosthesis of FIGURE 1;

FIGURE 5A is a perspective view of the self-expanding stent and the biocompatible material of the expandable prosthesis of FIGURE 1, illustrating the biocompatible material positioned on a mandrel within the lumen of the self-expanding stent during the manufacturing process of the present invention;

FIGURE 5B is a perspective view of the expandable prosthesis of FIGURE 1, illustrating the biocompatible material positioned on a mandrel and folded over the ends of the self-expanding stent to encapsulate the stent during the manufacture process of the present invention;

FIGURE 5C is a perspective view of the expandable prosthesis of FIGURE 1, illustrating the prosthesis at the completion of the manufacture process of the present invention;

FIGURE 6 is a flow chart illustrating the process of manufacturing the expandable prosthesis of FIGURE 1;

FIGURE 7A is a side elevational view of the expandable prosthesis of FIGURE 1, illustrating the expandable prosthesis positioned on a balloon catheter within a body vessel and in a radially compressed configuration;

FIGURE 7B is a side elevational view of the expandable prosthesis of FIGURE 1, illustrating the expandable prosthesis positioned on a balloon catheter within a body vessel and in a radially expanded configuration; and

FIGURE 8 is a flow chart illustrating a method of deploying the expandable prosthesis of FIGURE 1 within a body vessel according to the teachings of the present invention.

Detailed Description of the Preferred Embodiments

An expandable prosthesis 10 for restoring and maintaining the patency of body vessels, in particular blood vessels, according to the teachings of the present invention is illustrated in FIGURE 1. The expandable prosthesis 10 is deployable between a substantially radially compressed configuration, suitable for insertion into the body vessel, and a substantially radially expanded configuration for treatment of the body vessel. In the radial compressed configuration the diameter of the expandable prosthesis 10 is preferable less than the diameter of the body vessel being treated. Conversely, in the expanded configuration, the diameter of the prosthesis 10 is preferable slightly greater than or equal to the diameter of the body vessel. The expandable prosthesis 10 includes a self-expanding stent 12 and a biocompatible coating 14 attached to at least a portion of the outer surface 16 of the self-expanding-stent 12.

The expandable prosthesis 10 of the present invention is particularly suited for intraluminal delivery to a body vessel. The term "intraluminal" used herein means that delivery of the prosthesis 10 occurs at a target site within a body vessel, such as a blood vessel including, for example, coronary arteries, peripheral arteries, and cerebral arteries. The prosthesis 10 and the methods of the present invention, however, are not limited to use in the vascular system, and may be also employed in other body vessels, including, for example, the prostatic urethra to treat the prostate for benign prostate hyperplasia (BPH) or prostate cancer, the fallopian tube to treat strictures, and the brain parenchyma to treat Parkinson's disease.

Referring to FIGURES 2A and 2B, the self-expanding stent 12 includes a skeletal frame 20 having a plurality of generally axially extending members 22 connected by a plurality of generally transverse members 24 extending substantially transverse to the longitudinal axis and to the axial members 22. The self-expanding

stent 12 includes a first end 26 and a second end 28. The outer surface 16 extends between the first end 26 and the second end 28 of the stent 12. The stent 12 also includes an inner lumen 30. The self-expanding stent 12 can be deployed between a substantially compressed or crimped configuration, illustrated in FIGURE 2A and a substantially radially expanded configuration, illustrated in FIGURE 2B.

The self-expanding stent 12 is preferably constructed from materials which permit the size transition between the compressed and expanded configurations. Such materials include resilient polymers and special alloys that exhibit shape-memory properties or superelastic properties. Preferably, the self-expanding stent 12 is constructed from a shape-memory alloy that allows the stent 12 to deploy from the compressed configuration to the expanded configuration at slightly below mammalian body temperature, e.g. 32°C. Such shape-memory alloys include a nickel and titanium alloy commonly known as Nitinol.

Nitinol can exhibit two properties useful for the construction of stents and related medical prostheses - shape-memory and superelasticity. The primary factor for determining which of these two properties the Nitinol alloy exhibits is the austenite finish temperature (A_f), the temperature at which the transition of the alloy from the martensitic phase to the austenitic phase is complete. In the martensitic phase, the alloy is malleable. In the austenitic phase the alloy is resilient or superelastic. Superelasticity refers to the ability of the alloy to withstand large elastic deformations, e.g. up to 8% strain, at temperatures above the transition temperature A_f, but still return to the pre-constrained configuration without permanent deformation after the constraint is released.

Alternatively, a Nitinol alloy can be fabricated to exhibit shape-memory properties so that the alloy will undergo a transition from the martensitic phase to the austenitic phase, at a predetermined temperature. A Nitinol alloy stent can be fabricated to remain martensitic and in a constrained configuration below the predetermined transition temperature A_f but become austenitic and expand above the transition temperature A_f, e.g. at the body temperature or slightly below. The formation of stents

from Nitinol alloys having both superelastic and shape-memory properties is well described in the patent, scientific, and medical literature, and will not be described in detail herein.

With reference to FIGURES 3A-3B and 4, an exemplary process for manufacturing a self-expanding stent constructed from a Nitinol alloy having shape-memory properties will be described. A self-expanding stent 12 is fabricated from a Nitinol alloy and is maintained in the compressed configuration while in the martensitic phase, i.e. at a temperature below the transition temperature A_f, as illustrated in Figure 3A and in block 102 of FIGURE 4. The self-expanding stent 12 is then heated to a temperature above the transition temperature A_f, so that the Nitinol alloy completely enters the austenitic phase, block 104 of Figure 4. While in the austenitic phase, the self-expanding stent 12 is radially expanded on a tapered, stainless steel mandrel 50, as illustrated in FIGURE 3B and in block 108 of FIGURE 4. The self-expanding stent 12 is removed from the mandrel 50 in the expanded configuration, as shown in FIGURE 3C.

A stent constructed according to this process is self-expanding and exhibits shape memory properties. While in the austenitic phase, the stent 12 is resilient and superelastic and will return to the increased diameter of the expanded configuration when deformed. Upon lowering the temperature of the stent 12 below the transition temperature A_f, the stent 12 enters the martensitic phase and can be transformed to the compressed configuration, as the Nitinol alloy becomes malleable. The stent 12 can maintain the reduced diameter of the compressed configuration until heated above the transition temperature A_f, at which point the stent 12 expands on its own to the increased diameter of the expanded configuration.

The self-expanding stent 12 of the present invention is preferably constructed of a Nitinol alloy that exhibits shape-memory properties. A Nitinol alloy is preferred because of Nitinol's flexibility, resiliency, kink-resistance, memory retention, and durability. The self-expanding stent 12 of the present invention is not limited to a

Nitinol alloy construction, but can be constructed of alternative materials that exhibit resilient properties sufficient to permit the stent 12 to deploy between the compressed and expanded configurations. Additionally, the self-expanding stent 12 can be constructed of conventional alloys such as stainless steel in a configuration that exhibits self expansion characteristics. Examples of such stent include woven braided stents, such as the types described in U.S. Patent Nos. 4,655,771 (Wallsten); 4,954,126 (Wallsten) and 5,061,275 (Wallsten).

The biocompatible material 14 is attached to at least a portion of the outer surface 16 of the self-expanding stent 12 in the radially compressed configuration. The term "attached" used herein means that the biocompatible material 14 is coupled to the outer surface 16 of the self-expanding stent 12 in a manner that substantially precludes removal of the biocompatible material 14 from the stent 12 under normal conditions. The biocompatible material 14 thus is an integral component of the expandable prosthesis 10 during all phases of operation of the prosthesis 10, including intraluminal introduction in the radially compressed configuration and deployment to the radially expanded configuration. The biocompatible material 14 can be attached to the outer surface 16 of the self-expanding stent12, by suturing, adhesive or thermal bonding, mechanical bonding, welding, or the like. In the alternative, the biocompatible material 14 can be configured to encapsulate portions or all of the skeletal frame 20 of the self-expanding stent 12, as discussed in detail below, to thereby inhibit radial expansion of the self-expanding stent 12.

Referring to FIGURES 1 and 1A, the biocompatible coating 14 preferably extends along the outer surface 26 and within the lumen 30 of the self-expanding stent 12 to completely encapsulate the stent 12 within the biocompatible coating 14. The biocompatible coating 16 includes an inner layer 34 and an outer layer 36. Preferably, the inner layer 34 and outer layer 36 are coupled together in the spaces between the axial extending members 22 and the transverse members 24. The inner and outer layers 34 and 36 can be coupled by heating the layers and applying radial pressure to the layers. The structure and process of forming the layers 34 and 36 of the biocompatible coating

14 and coupling the layers 34 and 36 to the stent 12, as well as to each other, is described in detail in commonly owned U.S. Patent Application No. 08/759,877, incorporated herein by reference.

The biocompatible coating 16 is preferably constructed from expanded polytetrafluoroethylene (ePTFE) or similar fluoropolymer material. Alternative fluoropolymer materials suitable for use in the present invention include, for example, polytetrafluoroethylene or copolymers of tetrafluoroethylene with other monomers may be used. Such monomers may be ethylene, chlorotrifluoroethylene, perfluoro-alkoxytetrafluoroethylene, or fluorinated propylenes such as hexafluoropropylene.

The structure and process for of making ePTFE materials are described in commonly owned U.S. Patent Nos. 5,433,909 and 5,474,824, incorporated herein by reference, and will not be described in detail herein.

Alternatively, the biocompatible coating 16 can be constructed from a bioresorbable material such as polyglycolic acid polymers, polycaprolactone polymers, polylactic acid polymers or copolymer combinations thereof.

Preferably, the biocompatible coating 16 is attached to the self-expanding stent 12 in the radially compressed configuration. The biocompatible coating 16 thus acts as an integral retaining means to inhibit radial expansion of the stent 12 to the expanded configuration, regardless of the temperature of the self-expanding stent 12. In this manner, if the temperature of the self-expanding stent 12 is raised above the transition temperature A_f, such that the Nitinol alloy forming the stent enters the austenitic phase, the biocompatible material coating the stent 12 restrains the stent 12 from expanding to the increased diameter of the expanded configuration.

Referring to FIGURES 5A-5C and 6, an exemplary method of attaching the biocompatible coating 14 to the self-expanding stent 12 to form the expandable prosthesis 10 of the present invention will be described. Initially, the biocompatible

coating 14 is positioned on a cylindrical, stainless steel mandrel 56, block 202 of FIGURE 6. Next, the self-expanding stent 12, in the radially compressed configuration, is positioned on the mandrel 56, over the biocompatible coating 14, such that the biocompatible coating 14 is within the lumen 30 of the stent 12, as illustrated in FIGURE 5A and in block 204 of FIGURE 6. End portions 62 and 64 of the biocompatible coating 14 extend out of the lumen 30 of the stent at both the first and second ends 26 and 28 of the stent 12. The end portions 62 and 64 of the biocompatible coating 14 are then folded-over the first and second ends 26 and 28, respectively, of the stent 12, block 206 of FIGURE 6. The end portions 62 and 64 meet to form a single seam 70 and thus provide the outside layer 36 of the biocompatible coating 14 on the outside surface 14 of the stent 12, as shown in FIGURE 5B. The seam 70 preferably does not extend from the outside layer 36 completely through the inside layer 34. The expandable prosthesis 10 is heated to cause the outside layer 36 to shrink and coalesce with the inner layer 34 together about the stent 12, block 208. Preferably, the outer and inner layers 34 and 36 bond together at all points at which the layers contact so that the two layers form a unitary and non-delaminating cocoon surrounding the stent 12. Upon completion of the heating step, the expandable prosthesis 10 is removed from the mandrel 56, block 210. The completed expandable prosthesis 10 is shown in FIGURE 5C.

A method of deploying the expandable prosthesis 10 of the present invention within a body passage is illustrated in FIGURES 7A and 7B and in connection with the flow chart of FIGURE 8. Initially, the expandable prosthesis 10 of the present invention is positioned on a suitable intraluminal delivery instrument, such as a balloon catheter 90, block 300 of FIGURE 8. Intraluminal balloon catheters are well described in the patent, scientific, and medical literature, and will not be described in detail herein.

The expandable prosthesis 10 is positioned on the balloon catheter 90 with the self-expanded stent 12 in the radially compressed configuration. As discussed above, it is preferable for the transition temperature A_f of the Nitinol alloy forming the self-expanding stent 12 to be slightly less than the body temperature of the patient, e.g. 32°C.

Thus, when the expandable prosthesis 10 is inserted into the body vessel, the Nitinol alloy enters the austenitic phase and becomes flexible and resilient. The biocompatible coating 16, however, operates as an integrally mounted retaining means, inhibiting the self-expanding stent 12 from expanding to the expanded configuration, in the absence of an external, radially outward force on the stent. Accordingly, the biocompatible coating 16 eliminates the need for a separate, independent containment system, such as a delivery tube or sheath, to maintain the self-expanding stent 12 in the compressed configuration during delivery to the treatment site within the body vessel.

Next, the balloon catheter 90 is inserted into a body vessel, such as a blood vessel 85, over a guide wire 92 and positioned proximate a target site for treatment of the body vessel, as shown in FIGURE 7A and block 302 FIGURE 8. The "target site" within the body vessel can be a diseased region of the body vessel, such as a stenotic region of the body vessel. In the case of blood vessels, the target site can be a region of the blood vessel 90 that is occluded by arterial plaque 87.

The balloon catheter 90 is then positioned such that the expandable prosthesis 10 is adjacent the target site, block 304 of FIGURE 8. Next, the balloon 96 of the balloon catheter 90 is inflated to provide a radially-outward force on the expandable prosthesis 10, expanding the prosthesis 10 to the increased diameter of the expanded configuration, as shown in FIGURE 7B and in block 306 of FIGURE 8. The expandable prosthesis 10, in the expanded configuration engages the walls of the body vessel to effectively restore and maintain the patency of the occluded body vessel. Once the prosthesis 10 is expanded, the balloon 94 can be deflated and the balloon catheter withdrawn from the body vessel, block 308.

Preferably, the balloon 94 expands the expandable prosthesis 10 such that the biocompatible coating 16 expands beyond the elastic limits of the material forming the biocompatible coating 14, while concomitantly maintaining the material forming the self-expanding stent 12 within its elastic limits. By maintaining the stent 12 material within its elastic limits, the stent 12 remains flexible and resilient. The flexibility and

resilient properties of the stent 12 are important for permitting the stent to accommodate motion of the body vessel and tissue surrounding the body vessel without fracturing or separating from the walls of the body vessel.

It will thus be seen that the invention efficiently attains the objects made apparent from the preceding description. Since certain changes may be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are to cover all generic and specific features of the invention described herein, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described the invention, what is claimed as new and desired to be secured by Letters Patent is:

1. An expandable prosthesis comprising:

a self-expanding stent deployable between a substantially radially compressed configuration and a substantially radially expanded configuration, the self-expanding stent including a first and a second end and an outer surface extending therebetween, and

a biocompatible coating attached to at least a portion of the outer surface of the self-expanding stent in the radially compressed configuration to inhibit radial expansion of the self-expanding stent to the radially expanded configuration.

2. The prosthesis of claim 1, wherein the self-expanding stent is constructed from a material having shape-memory properties.

3. The prosthesis of claim 2, wherein the material having shape-memory properties is an alloy of nickel and titanium.

4. The prosthesis of claim 3, wherein the nickel and titanium alloy is Nitinol.

5. The prosthesis of claim 1, wherein the biocompatible coating is expanded polytetrafluoroethylene (ePTFE).

6. The prosthesis of claim 1, wherein the biocompatible coating extends between the first and second ends of the self-expanding stent.

7. The prosthesis of claim 1, wherein the self-expanding stent includes an inner surface, and

wherein the biocompatible coating is folded-over the first end of the self-expanding stent and is attached to at least a portion of the inner surface of the self-expanding stent.

8. The prosthesis of claim 7, wherein the biocompatible coating is folded-over the second end of the stent and is attached to a second portion of the inner surface of the self-expanding stent.

9. The prosthesis of claim 1, wherein the self-expanding stent includes an inner surface extending between the first and second ends, and

wherein the biocompatible coating is attached to the inner and outer surfaces and extends between the first and second ends to encapsulate the self-expanding stent.

10. The prosthesis of claim 1, wherein the biocompatible coating is constructed from a bioresorbable material.

11. The prosthesis of claim 10, wherein the bioresorbable material is selected from the group consisting of polyglycolic acid polymers, polycaprolactone polymers, polylactic acid polymers and copolymer combinations thereof.

12. A prosthesis comprising:

a self-expanding stent deployable between a substantially radially compressed configuration and a substantially radially expanded configuration, the self-expanding stent including a first and a second end and an outer surface extending therebetween, and

means for retaining the self-expanding stent in the radially compressed configuration, the retaining means being integrally mounted to the self-expanding stent in the radially compressed configuration.

13. The prosthesis of claim 12, wherein the self-expanding stent is constructed from a material having shape-memory properties.

14. The prosthesis of claim 13, wherein the material having shape-memory properties is an alloy of nickel and titanium.

15. The prosthesis of claim 14, wherein the nickel and titanium alloy is Nitinol.

16. The prosthesis of claim 12, wherein the retaining means is a biocompatible coating attached to at least a portion of the outer surface of the self-expanding stent.

17. The prosthesis of claim 16, wherein the biocompatible coating is expanded polytetrafluoroethylene (ePTFE).

18. The prosthesis of claim 16, wherein the biocompatible coating extends between the first and second ends of the self-expanding stent.

19. The prosthesis of claim 16, wherein the self-expanding stent includes an inner surface, and

wherein the biocompatible coating is folded-over the first end of the self-expanding stent and is attached to at least a portion of the inner surface of the self-expanding stent.

20. The prosthesis of claim 19, wherein the biocompatible coating is folded-over the second end of the stent and is attached to a second portion of the inner surface of the self-expanding stent.

21. The prosthesis of claim 16, wherein the self-expanding stent includes an inner surface extending between the first and second ends, and

wherein the biocompatible coating is attached to the inner and outer surfaces and extends between the first and second ends to encapsulate the self-expanding stent.

22. An expandable prosthesis comprising:

a self-expanding stent deployable between a substantially radially compressed configuration and a substantially radially expanded configuration, the self-expanding stent including a first and a second end and an outer surface extending therebetween, and

a biocompatible coating attached to the outer surface of the self-expanding stent, the biocompatible coating capable of being plastically deformed.

23. An expandable prosthesis comprising:

a self-expanding stent having a first and a second end and an outer surface extending therebetween, the self-expanding stent having a first diameter which permits delivery of the self-expanding stent into a body passage, and a second, expanded diameter suitable for treatment of the body passage, and

a layer of biocompatible material attached to at least a portion of the outer surface of the self-expanding stent, the layer being deformable between a first state sized to restrain the self-expanding stent to the first diameter, and a second, expanded state, the layer deforming to the second, expanded state upon expansion of the self-expanding stent to the second diameter by a radially, outward extending force.

24. The prosthesis of claim 23, wherein the layer of biocompatible material is expanded beyond its elastic limit during deformation to the second, expanded state such the biocompatible material is plastically deformed.

25. The prosthesis of claim 23, wherein the self-expanding stent is constructed from a material having shape-memory properties.

26. The prosthesis of claim 25, wherein the material having shape-memory properties is an alloy of nickel and titanium.

27. The prosthesis of claim 26, wherein the nickel and titanium alloy is Nitinol.

28. The prosthesis of claim 23, wherein the biocompatible material is expanded polytetrafluoroethylene (ePTFE).

29. The prosthesis of claim 23, wherein the layer of biocompatible material extends between the first and second ends of the self-expanding stent.

30. The prosthesis of claim 23, wherein the self-expanding stent includes an inner surface, and

wherein the prosthesis further comprises a second layer of biocompatible material attached to the inner surface of the self-forming stent.

31. A method of forming an expandable prosthesis, the method comprising the steps of:

providing a self-expanding stent having first and second ends and outer and inner surfaces extending therebetween, the self-expanding stent being deployable between a substantially radially compressed configuration and a substantially radially expanded configuration, and

coating the self-expanding stent in the radially compressed configuration with a biocompatible material to retain the stent in the radially compressed configuration.

32. The method of claim 31, wherein the step of coating includes coating at least a portion of the outer surface of self-expanding stent.

33. The method of claim 31, wherein the self-expanding stent is constructed from a material having shape-memory properties.

34. The method of claim 33, wherein the material having shape-memory properties is an alloy of nickel and titanium.

35. The method of claim 34, wherein the nickel and titanium alloy is Nitinol.

36. The method of claim 31, wherein the biocompatible coating is expanded polytetrafluoroethylene (ePTFE).

37. The method of claim 31, wherein the step of coating further includes the step of coating the outer surface of the self-expanding stent from the first end to the second end of the stent.

38. The method of claim 31, further comprising the step of coating at least a portion of the inner surface of the self-expanding stent.

39. A method of introducing an expandable prosthesis into a body passage, the method comprising the steps of:

providing an expandable prosthesis including

a self-expanding stent having a first and a second end and an outer surface extending therebetween and being deployable between a substantially radially compressed configuration and a substantially radially expanded configuration, and

a biocompatible coating attached to at least a portion of the outer surface of the self-expanding stent,

disposing the prosthesis on a catheter,

inserting the prosthesis and the catheter within the body passageway, the biocompatible coating retaining the self-expanding stent in the radially compressed configuration.

40. The method of claim 39, wherein the self-expanding stent is constructed from a material having shape-memory properties.

41. The method of claim 40, wherein the material having shape-memory properties is an alloy of nickel and titanium.

42. The method of claim 41, wherein the nickel and titanium alloy is Nitinol.

43. The method of claim 39, wherein the biocompatible coating is expanded polytetrafluoroethylene (ePTFE).

44. A method of deploying an expandable prosthesis in a body passage, the method comprising the steps of:

providing an expandable prosthesis including

a self-expanding stent having a first and a second end and an outer surface extending therebetween, and

a biocompatible coating attached to at least a portion of the outer surface of the self-expanding stent,

disposing the prosthesis on a catheter,

inserting the prosthesis and the catheter within the body passageway, and

expanding the prosthesis at a desired location in the body passage by applying a radially outward force on the prosthesis to place the biocompatible material into contact with the body passage, the step of expanding and radially deforming the biocompatible coating beyond its elastic limit.

45. The method of claim 44, wherein the self-expanding stent is constructed from a material having shape-memory properties.

46. The method of claim 45, wherein the material having shape-memory properties is an alloy of nickel and titanium.

47. The method of claim 46, wherein the nickel and titanium alloy is Nitinol.

48. The method of claim 44, wherein the biocompatible coating is expanded polytetrafluoroethylene (ePTFE).

49. The method of claim 44, further comprising the step of providing the radially outward force on the prosthesis by inflating a catheter-deployed balloon within the self-expanding stent.

FIG. 1

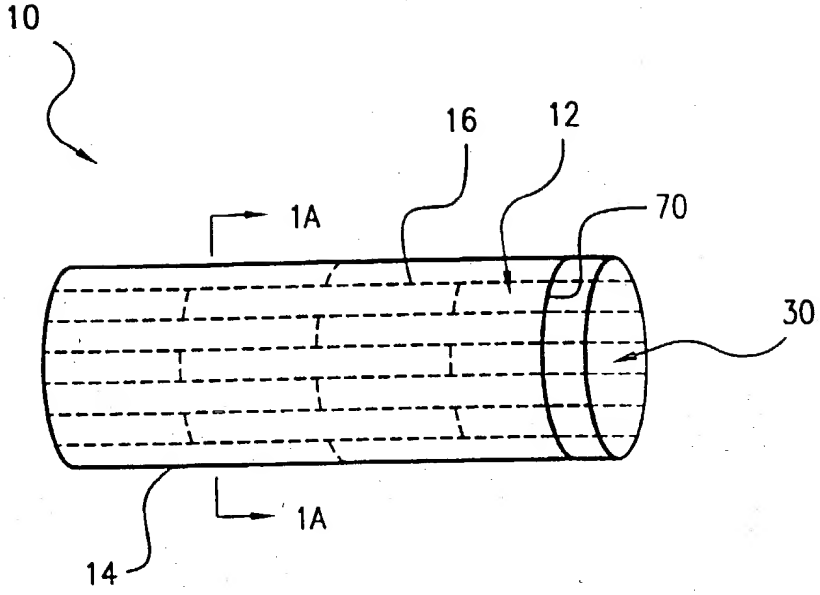


FIG. 1A

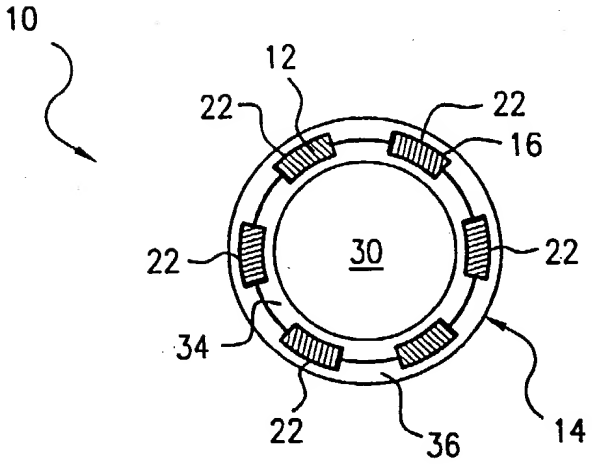


FIG. 2A

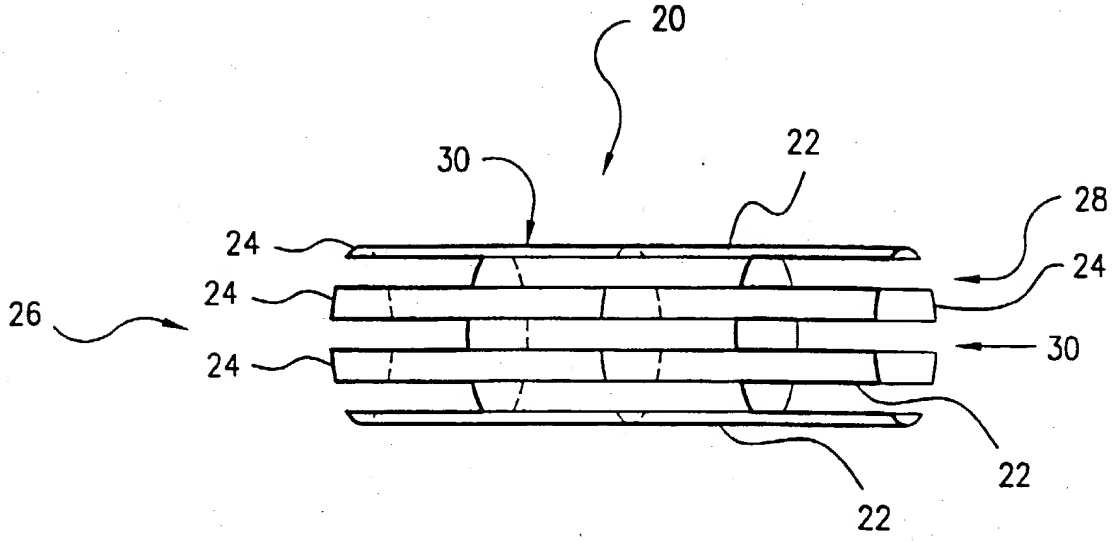


FIG. 2B

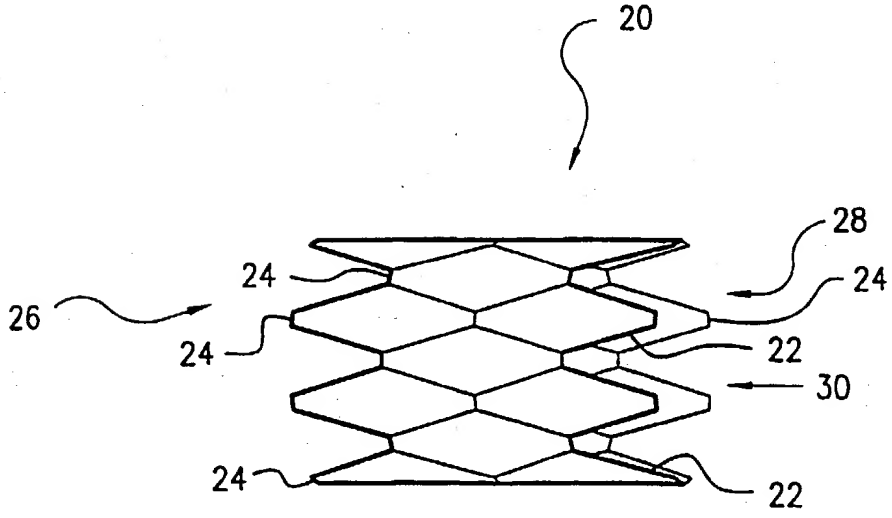


FIG. 3A

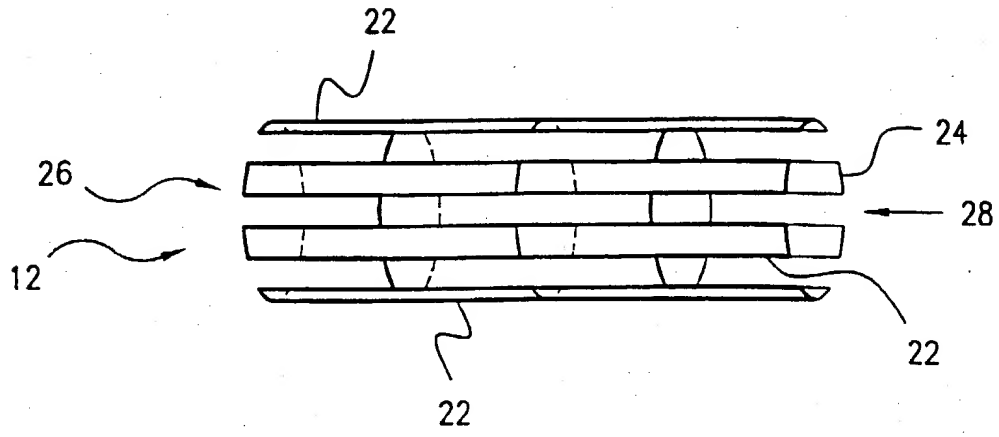


FIG. 3B

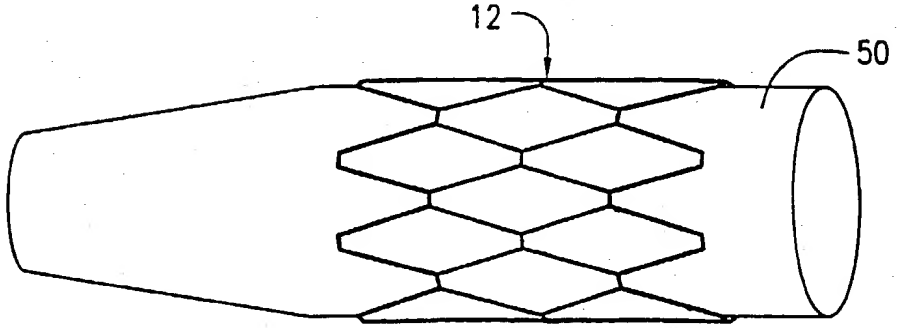


FIG. 3C

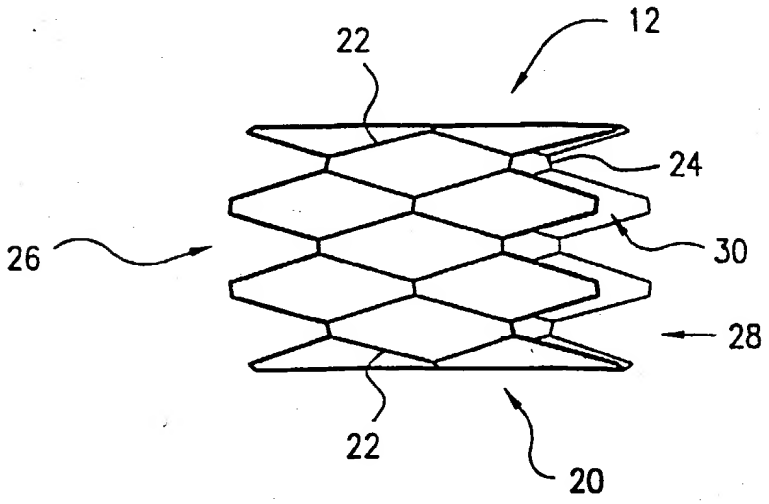


FIG. 4

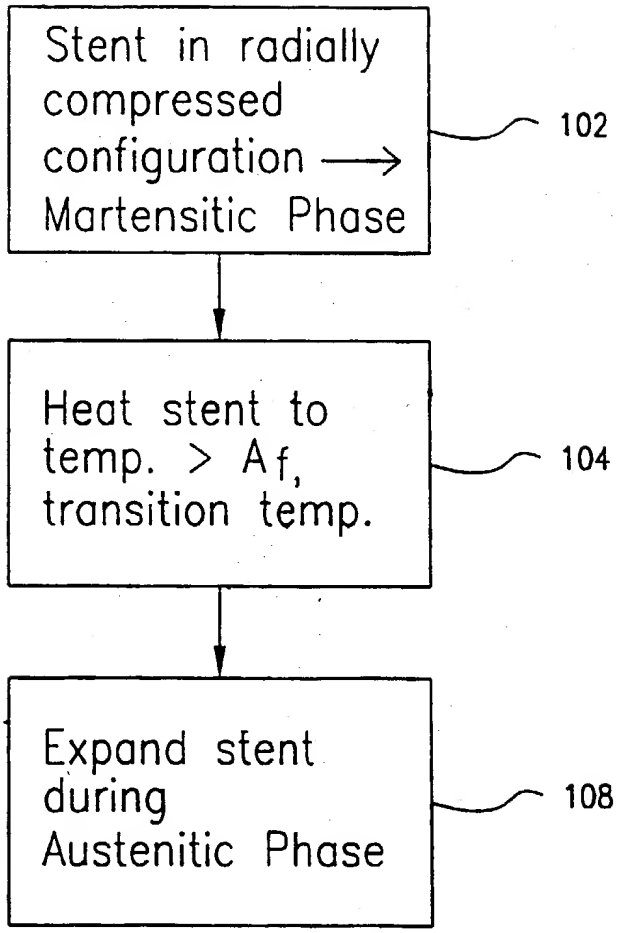

Stent in radially compressed configuration → Martensitic Phase
102
Heat stent to temp. > A_f, transition temp.
104
Expand stent during Austenitic Phase
108

FIG. 5A

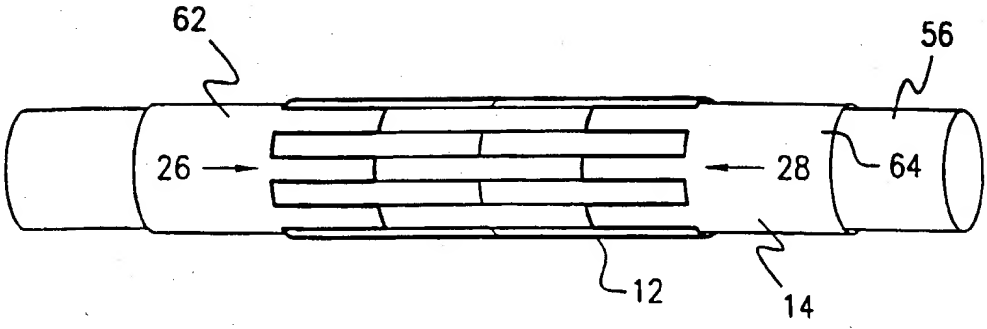


FIG. 5B

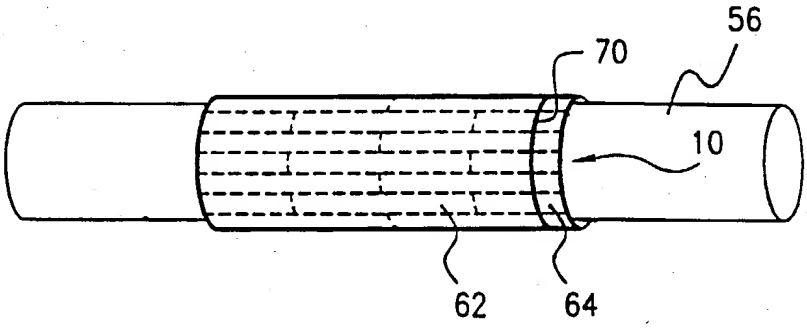


FIG. 5C

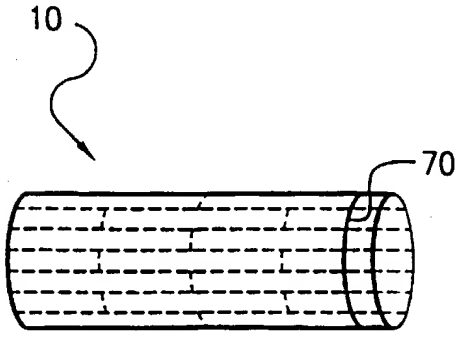


FIG. 6

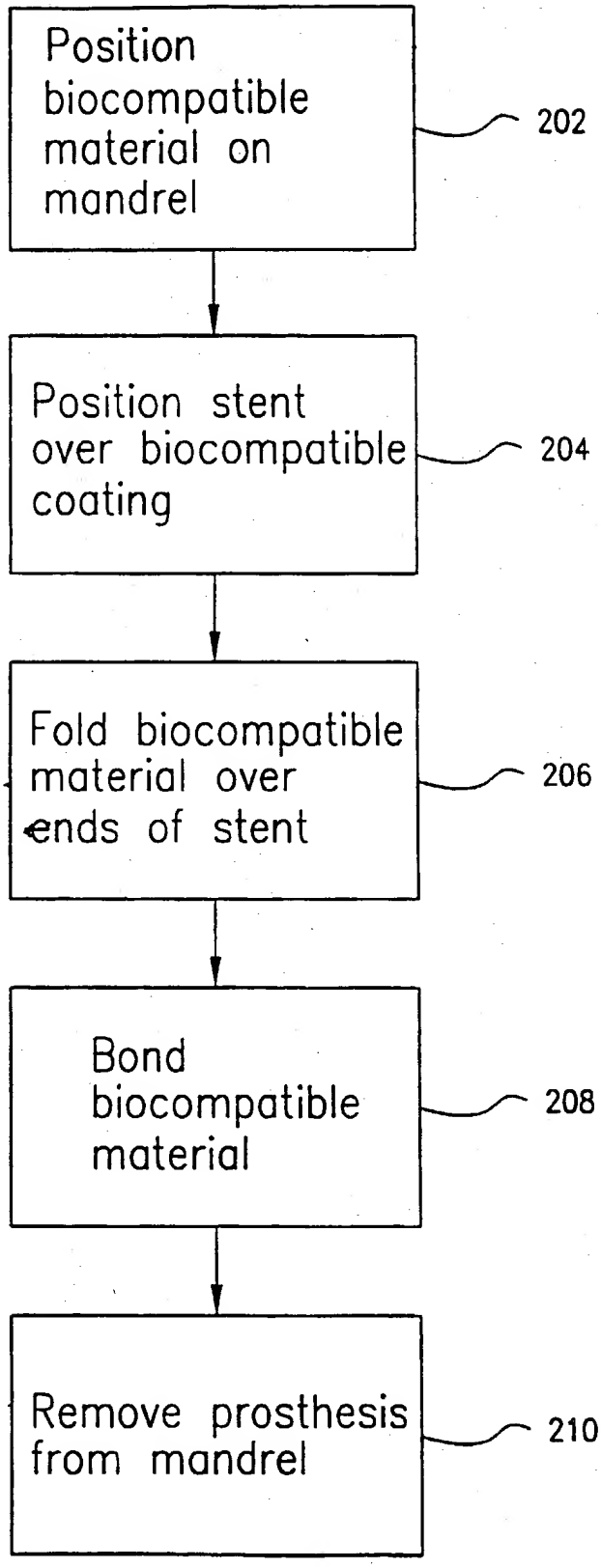

Position biocompatible material on mandrel
202
Position stent over biocompatible coating
204
Fold biocompatible material over ends of stent
206
Bond biocompatible material
208
Remove prosthesis from mandrel
210

FIG. 7A

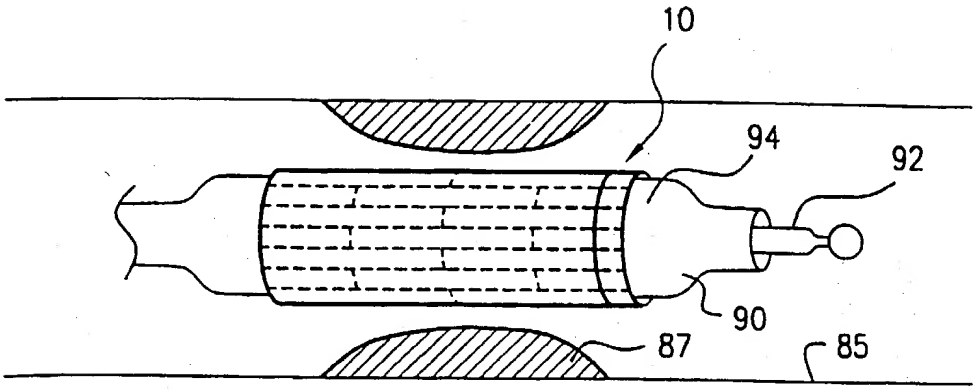


FIG. 7B

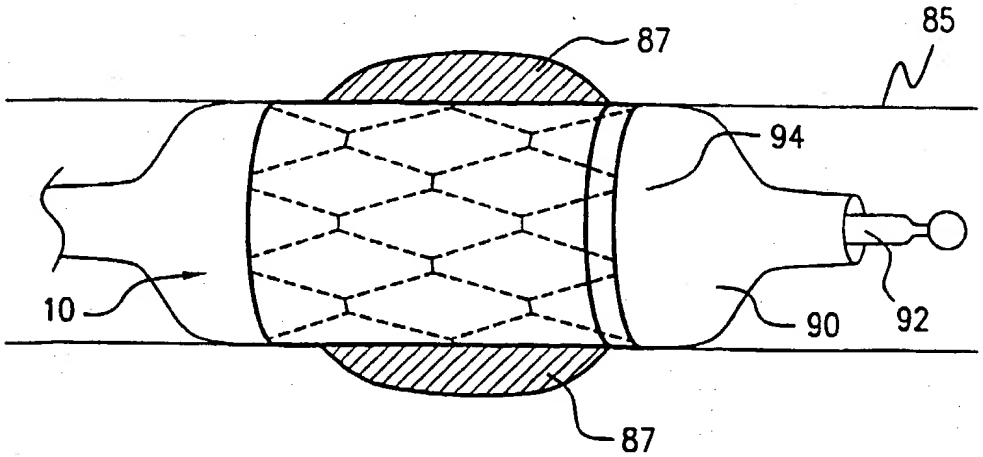
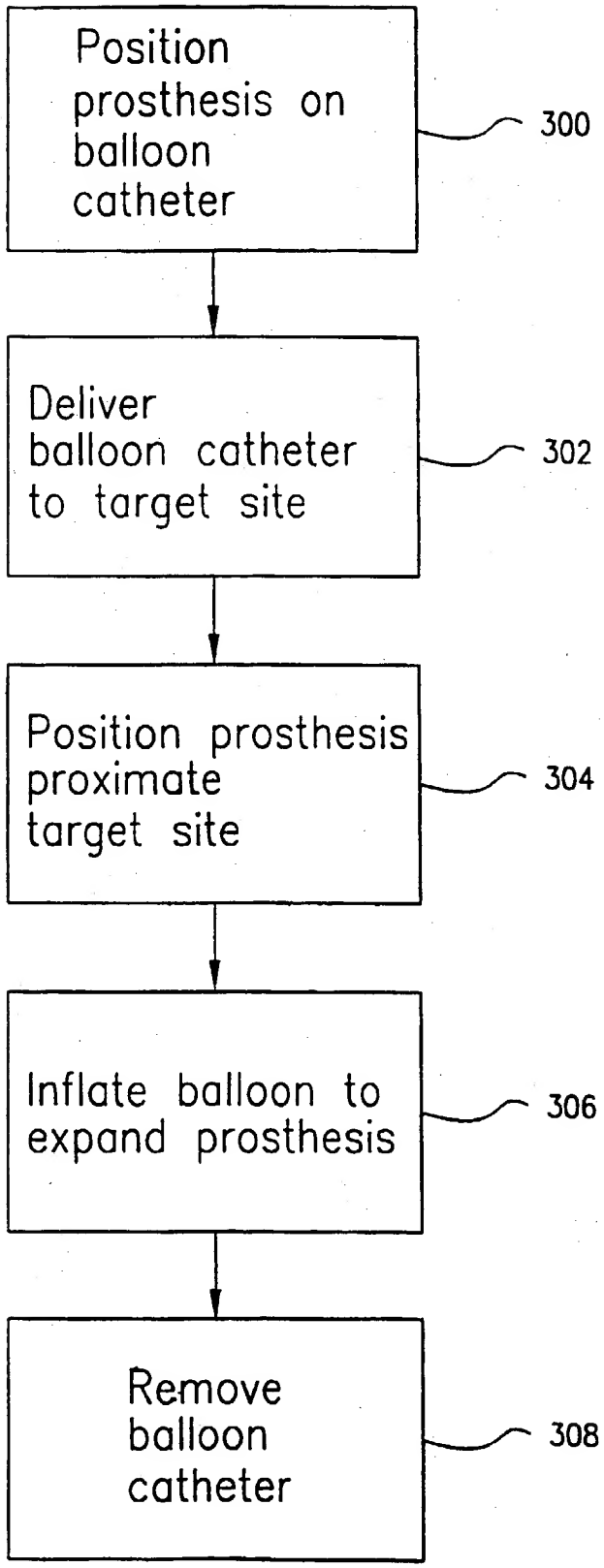


FIG. 8


Position prosthesis on balloon catheter
300
Deliver balloon catheter to target site
302
Position prosthesis proximate target site
304
Inflate balloon to expand prosthesis
306
Remove balloon catheter
308

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/US 99/30582

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L31/10 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passage	Relevant to claim No.
X	US 5 810 870 A (HOUSE WAYNE D ET AL) 22 September 1998 (1998-09-22) example 1 claims 1,9,11	1-9, 12-49
X	US 5 788 626 A (THOMPSON PAUL J) 4 August 1998 (1998-08-04) claims 1,10	1-9, 12-49
A	US 4 994 066 A (VOSS GENE A) 19 February 1991 (1991-02-19) abstract	1,12,22, 23,31, 39,44

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 April 2000	17/05/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Heck, G

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/US 99/30582

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 607 467 A (FROIX MICHAEL) 4 March 1997 (1997-03-04) column 2, line 34 - line 57 claim 1	1,12,22, 23,31, 39,44

1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/30582

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 39-49
because they relate to subject matter not required to be searched by this Authority, namely:

Remark: Although claim(s) 39-49 is(are) directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 39-49 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.1

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte nal Application No
PCT/US 99/30582

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5810870 A	22-09-1998	US 5735892 A	07-04-1998
		AU 6824994 A	14-03-1995
		CA 2167944 A	23-02-1995
		EP 0714269 A	05-06-1996
		JP 9501584 T	18-02-1997
		WO 9505132 A	23-02-1995
		US 5700285 A	23-12-1997
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US 5788626 A	04-08-1998	AU 714991 B	13-01-2000
		AU 7187796 A	29-05-1997
		CA 2190717 A	22-05-1997
		EP 0775472 A	28-05-1997
		JP 9173467 A	08-07-1997
US 4994066 A	19-02-1991	NONE	
US 5607467 A	04-03-1997	US 5258020 A	02-11-1993
		US 5163952 A	17-11-1992